UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,484	07/13/2001	Moncef Jendoubi	252/159	3711

22249 7590 03/05/2002

LYON & LYON LLP
633 WEST FIFTH STREET
SUITE 4700
LOS ANGELES, CA 90071

EXAMINER
COUNTS, GARY W

ART UNIT	PAPER NUMBER
1641	3

DATE MAILED: 03/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/905,484	Applicant(s) JENDOUBI, MONCEF	
	Examiner Gary W. Counts	Art Unit 1641	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *9-14 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 15-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8 and 15-20, drawn to an array of at least 10 antibodies arranged in discrete areas of a solid support, classified in class 436, subclass 518.

II. Claims 9-13, drawn to a method to analyze gene expression, classified in class 435, subclass 6.

III. Claim 14, drawn to a method of diagnosing a disease in an organism, classified in class 530, subclass 387.1.

IV. Claim 21, drawn to a method to detect the gene product expression pattern of a disease, classified in class 435, subclass 7.1.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process for using the product as claimed can be practiced with another materially different product such as a flow cytometer.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process

for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as in claim 14.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as in claim 14.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, producing antibodies by DNA immunization and also correlating the binding events to the disease of claim 14 are not required by the claims of 9-13.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, obtaining sample containing protein derived from each of normal and disease related cells and exposing each sample to an array of at least 10 antibodies of as claimed in claim 21 are not required by the claims of 9-13.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, producing antibodies by DNA immunization and also correlating the binding events to the disease of claim 14 are not required by claim 21.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for one group is not required for other restriction for examination purposes as indicated is proper.

During a telephone conversation with Kurt Mulville on October 17, 2001 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-8 and 15-20. Affirmation of this election must be made by applicant in replying to this Office action. Claims 9-14 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-8 and 15-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 2 "the antigen" there is insufficient antecedent basis for this limitation.

Claim 1, line 3 "the antibody" there is insufficient antecedent basis for this limitation. Which of the 10 antibodies is applicant referring to?

Claim 1 is vague. It is unclear if the 10 antibodies are the same or different antibodies.

Claim 1, the recitation "correlated to a polynucleotide sequence encoding the antigen" is vague. It is unclear if the antibody binds to the polynucleotide sequence or to the antigen.

Claim 6, the recitation "component of murine sera" is vague. It is unclear what applicant intends.

Claim 7, the recitation "at least 10 antibodies is a value between 100 and 10,000" is vague and indefinite. It is unclear if the numerical values of 100 and 10,000 are units of measure.

Claim 8 the recitation "a sample containing a protein derived from human cells reflecting disease" is vague and indefinite. It is unclear if the protein reflects the disease or if the human cells reflect the disease, i.e. are they tumor cells. It is also indefinite as to what type of disease is being reflected.

Claim 15, line 3 "the protein" there is insufficient antecedent basis for this limitation.

Claim 16, "15wherein" should be -- 15 wherein --.

Claim 19, "the composition" there is insufficient antecedent basis for this limitation.

Claim 20 "component of murine sera" is vague. It is unclear what applicant intends.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-8, and 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al (US Patent 6,329,209) in view of Kamb et al (US Patent 6,218,146).

Wagner et al disclose arrays of antibodies which are arranged in discrete, known regions on the portions of a substrate (solid support) surface and wherein each patch comprises antibodies attached thereon. Wagner et al disclose that the antibodies of a given patch are capable of binding a particular antigen and that the array comprises a plurality of different antibodies, each of which is capable of binding a particular antigen (col 2, line 63 – col 3, line 9). Wagner et al disclose that these antibodies may be polyclonal or monoclonal antibodies, or antibody fragments (col 13, lines 6-20). Wagner et al also disclose that the arrays comprise at least about 10 different antibodies and more preferably, at least about 100 different antibodies and may contain 10,000 different antibodies (col 11, lines 1-42). Wagner et al also disclose that the array can be

used as a diagnostic tool in evaluating the status of a tumor or other diseased tissue in a human patient (col 11, lines 11-27) and (col 37, lines 59-67). Wagner et al also disclose using the array with a biochip to form a device (col 37, line 54-59).

Wagner et al differ from the instant invention in failing to disclose the antibody correlating to a polynucleotide sequence.

Kamb et al disclose both monoclonal and polyclonal antibodies which are capable of specifically binding to polynucleotide sequences. Kamb et al also disclose that the polyclonal antibodies may be raised by immunizing mice (col 14, lines 58-64). These antibodies are useful in assays as well as pharmaceuticals (col 14, lines 32-37) and also provides the means necessary for production of gene-based therapies directed at cancer cells (col 8, lines 9 and 10).

It would have been obvious to one of ordinary skill in the art to incorporate the use of polynucleotide sequence specific antibodies as taught by Kamb et al into the array of Wagner et al because Kamb et al show that these antibodies are useful in assays as well as pharmaceuticals and also provides the means necessary for production of gene-based therapies directed at cancer cells.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Chin et al (US Patent 6,197,599) disclose a device comprised of a solid support and multiple immobilized agents for protein detection. The immobilized agents are mainly proteins, such as antibodies and recombinant proteins. The antibodies are

individually deposited in a predetermined order, so that each of the antibodies can be identified by the specific position it occupies on the support (abstract).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gary W. Counts
Examiner
Art Unit 1641
February 11, 2002

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
02/21/02